REMARKS

Claims 14, 17, 19, 20, 32-34, 36-38, 40-42 and 45-48 and 50-51 are pending in the application with entry of this Amendment. Claims 32-34, 37, 42, 45-46 and 50 are currently amended. Claims 44 and 49 are currently canceled without prejudice. New claim 51 is added. The amendments and new claim do not present new matter. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejection

Applicant acknowledges that the prior rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,685,466 to Rau ("Rau") in view of U.S. Patent No. 6,228,082 to Baker *et al.* ("Baker") was withdrawn.

II. Rejection Under 35 U.S.C. §112¶1

Claims 32-34 stand rejected under 35 U.S.C. §112¶1 as allegedly failing to satisfy the written description requirement based on the allegation that "without the tissue stimulation element piercing the tissue" is not explicitly supported by the specification.

"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP §2163. "While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." MPEP §2163. Thus, while the Office action remarks refer to only explicit support in the specification, this does not accurately characterize how the written description may be satisfied.

Claims 32-34 satisfy the written description requirement in view of the explicit and inherent disclosure provided by the specification and drawings. The subject application discloses tissue stimulation elements 702 and tissue piercing members 708. A tissue piercing member 708, as its name implies, has a sharpened end for piercing tissue. The subject application, however, does not explain that a tissue stimulation element pierces tissue. Instead, the subject application explains, with reference to the embodiment illustrated in Figs. 33-36, for example, that the "carrier 706 and tissue piercing members 708 are dimensioned and positioned relative to one another such that the carrier will be deflected (and stressed) when the piercing members are placed into tissue. As a result, the stimulation electrodes 702 will be forced (or

'biased') against the tissue when the piercing members 708 engage the tissue" which, as explained above, involves the tissue piercing members piercing tissue.

Thus, the subject application differentiates a tissue piercing member having a sharpened tip for piercing tissue and a tissue stimulation element that does not pierce tissue and instead is pushed or biased against tissue. Consistent with this conclusion is the subject application showing tissue stimulation elements 702 that are in the form of ring-shaped stimulation electrodes or relatively small, low profile devices located on opposite ends of a base or anchor such that when the tissue piercing member pierces tissue, the stimulation electrodes are pushed against tissue, *i.e.*, do not pierce tissue, in contrast to piercing members that are "dimensioned and positioned" to have a sharpened end in a central part of the device for piercing tissue to press the stimulation elements "against" the tissue. These structural attributes are also shown in various drawings. *See, e.g.*, Figs. 33-34 (illustrating clear differentiation between a tissue piercing member 708 having a sharpened end for piercing tissue and ring-type stimulation electrodes 702 on opposite sides of an anchor); Fig. 37 (also illustrating clear differentiation between helical tissue piercing member having sharpened end and ring-type electrodes 702 on opposite ends of an anchor); Fig. 39 (illustrating a device that is operably by not piercing tissue at all such that the tissue stimulation electrodes 702 do not pierce tissue).

Thus, claims 32-34 do indeed satisfy the written description requirement, particularly considering that it is clear that the subject application distinguishes and differentiates tissue piercing elements having sharpened ends and that are dimensioned and positioned for piercing tissue and stimulation electrodes that are not structurally configured or arranged for this purpose and that the subject application describes embodiments in which a stimulation and sensing device is placed "onto" or "against" tissue to force stimulation electrodes 702 "into close contact with the tissue" which, as is well understood, does not involve a tissue stimulation element piercing of tissue. These conclusions are also consistent with the fact that the subject application does not explain that a tissue stimulation is configured or utilized for piercing tissue and does not explain that a tissue stimulation element has a sharpened tip for this purpose. A person skilled in the art would readily appreciate the differences between tissue piercing members and tissue stimulation elements and would readily recognize that tissue stimulation elements do not pierce tissue, do not have a sharpened end for piercing tissue, and are not configured and arranged for piercing tissue.

For purposes of clarification, and consistent with these explicit and inherent disclosures provided by the written description and various drawings, the specification has been amended to further specify that the stimulation electrodes 702 do not pierce tissue. MPEP §2163.07(a) ("By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter); MPEP §2163.07 ("Mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible).

Accordingly, it is respectfully submitted that the rejection of claims 32-34 under 35 U.S.C. §112¶1 is moot and be withdrawn.

III. Rejection Under 35 U.S.C. §112¶2

Claims 14, 17, 19, 20, 32-34, 36, 37, 40-42 and 45-50 stand rejected under 35 U.S.C. §112¶2 as allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention on the basis that "stimulation element too small to form a transmural myocardial lesion' is indefinite. Applicant respectfully submits that the allegation is misplaced and be withdrawn since the claims do include discernible limitations that, when read in light of the specification, apprise those skilled in the art how the invention is used and the scope of the invention, and is nevertheless moot in view of the claims as amended. MPEP §2173.02 ("a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible"), citing *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term "surrender value protected investment credits" which was not defined or used in the specification was discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence"). MPEP §2173.05(a) ("If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112, second paragraph) demands no more.").

Initially, it is alleged that "Claims 32-34 recite 'stimulation element too small to form a transmural myocardial lesion' which is indefinite…" Office Action (p. 2). This allegation is not

correct, but claim 41, which depends from claim 34, does recite a limitation directed to a stimulation element being too small to form a transmural myocardial lesion.

It is further alleged that "stimulation element too small to form a transmural myocardial lesion" is indefinite based on the argument that it is the combination of the size, configuration and energy delivery that determine whether a transmural myocardial lesion is formed and, therefore, that this limitation is considered to be a functional limitation. Applicant respectfully submits the rejection is misplaced, but in order to advance prosecution to address Office action allegations that are inconsistent with the explicit and inherent disclosure provided by the subject application, claims 32-34 are amended to clarify the differences between devices that emit ablative energy and devices that do not (e.g., stimulation elements that are too small to form a transmural myocardial lesion). Specifically, to clarify the structural features and configurations of stimulation elements in contrast to ablative devices, claims 32 and 33 are amended to recite *inter alia* "a tissue stimulation element having a diameter of about 0.5mm to 1.0mm and being configured to emit non-ablative stimulation energy that is applied to tissue to determine whether a transmural myocardial lesion has been formed." Thus, claims 32 and 33, in addition to reciting structural features directed to the size of the stimulation element being too small to form a transmural myocardial lesion, also recite that the diameter of a tissue stimulation element is "about 0.5mm to 1.0mm" further defining how the stimulation is too small to form a transmural myocardial lesion, and also recite that the stimulation element is configured to emit non-ablative stimulation energy, thereby rendering moot any remarks regarding utilizing higher level, ablative energy in combination with a stimulation element that is too small to form a transmural myocardial lesion. Similarly, claim 34 is amended to recite *inter alia* "a first tissue stimulation element and a second tissue stimulation element that are configured to emit non-ablative stimulation energy that is applied to tissue to determine whether a transmural myocardial lesion has been formed."

Thus, a person skilled in the art would readily understand the differences between devices that are configured and used for ablation and devices that are not used for this purpose and instead are configured to emit non-ablative, stimulation energy through a stimulation element that is too small to form a transmural myocardial lesion, particularly when these claims are read in light of the specification, which specifically refers to stimulation elements that are too small to form a transmural myocardial lesion multiple times and also provides examples of

dimensions of the stimulation elements. For example, the subject application explains "The exemplary stimulation electrodes 702 may be ring electrodes that are about 0.5 mm to 2 mm in length and are otherwise similar to the ring-shaped stimulation electrodes described above. Alternatively, the stimulation electrodes may be relatively small, low profile devices (e.g. about 0.5 mm to 1 mm in diameter, and about 0.01 mm thick) located on the tissue facing side of the carrier 706." These structural attributes are not "functional" as alleged.

Claim 37 was previously amended by crossing out the "s" but since that amendment was not entered, this typographical error is illustrated in another manner.

Accordingly, it is respectfully submitted that the rejection of claims 14, 17, 19, 20, 32-34, 37, 37, 40-42 and 45-50 under 35 U.S.C. §112¶2 is moot and be withdrawn.

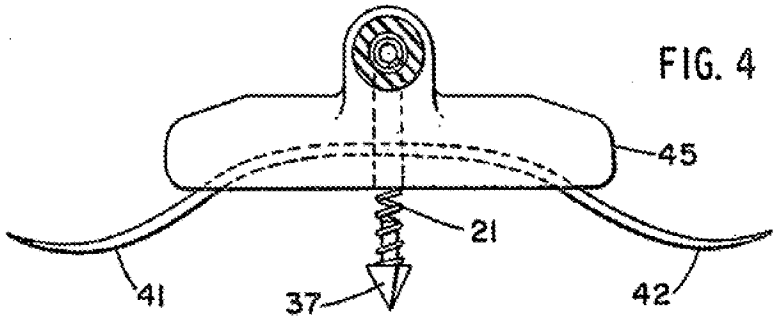
IV. Claims 14, 17, 19, 20, 32, 33 and 42 Are Patentable Over Hess and Baker

Independent claims 32 and 33 and respective dependent claims 14, 17, 19, 20 and 42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,144,890 to Hess ("Hess") in view of U.S. Patent No. 6,228,082 to Baker *et al.* ("Baker"). Applicant respectfully submits that the rejection is moot.

Hess fails to disclose, and is not related to, "means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure at a first tissue structure location and pressing the stimulation element against the single side of the tissue structure at a second tissue structure location different than the first tissue structure location, wherein the stimulation element does not have a sharpened end and is positioned relative to the means for securing the surgical apparatus to the tissue structure such that the tissue stimulation element is pressed against the single side of the issue structure and does not pierce the tissue structure" as recited in claim 32 and "an anchor carrying the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue at a first location and to press the stimulation element against the tissue at a second location different than the first location, wherein the stimulation element does not have a sharpened end and is positioned relative to a portion of the anchor that pierces tissue such that the tissue stimulation element is pressed against the tissue and does not pierce the tissue" as recited in claim 33.

It is alleged that the helical wire electrode 21 in Hess is a "stimulation element" as recited in claims 32 and 33. It is also conceded in the Office action that the highly sharpened tip

37 pierces tissue. Fig. 4 of Hess, one of the figures cited in the Office action, is reproduced below for reference.



As shown in Hess, Fig. 4 above, the helical wire 21 is coaxial with and extends around a base from which the highly sharpened tip 37 extends and to an end of the tip 37. Since these cited components are coaxially disposed, they contact or engage the same tissue location. Consequently, Hess fails to disclose, and is not related to, a structure for piercing tissue at a first location and pressing stimulation electrode against tissue at a second, different location. In this regard, Hess describes a structural configuration that is the opposite of the structure configuration recited in claims 32 and 33. Moreover, given the particular coaxial structure described by Hess, the cited reference teaches away from claims 32 and 33.

Given this coaxial structure that is applied to the same tissue location, Hess also fails to disclose the stimulation element not having a sharpened end and being positioned relative to the means for securing the surgical apparatus to the tissue structure such that the tissue stimulation element is pressed against the single side of the tissue structure and does not pierce the tissue as recited in claim 32 and the stimulation element not having a sharpened end and being positioned relative to a portion of the anchor that pierces tissue such that the tissue stimulation element is pressed against the tissue and does not pierce the tissue as recited in claim 33. Once again, Hess describes a structural configuration that is the opposite of the structure configuration recited in claims 32 and 33 and teaches away from claims 32 and 33.

For example, contrary to what is alleged, Hess specifically explains that the cited helical electrode 21 is structured for penetrating tissue and does in fact penetrate tissue during use. Notably, this section of Hess was not addressed in the Office Action since it clearly contradicts and renders the rejection moot. In particular, Hess explains:

> While an electrode of the type indicated at 21 may be introduced into the cardiac tissue by means of a stab wound provided in advance, a preferred method of permitting the electrode [21] to pierce the cardiac tissue is to provide a highly sharpened, multifaceted point, as indicated at 37. Hess (col. 2, lines 56-61) (emphasis added).

Thus, it is clear from the cited section of Hess above that the cited reference fails to disclose wherein the stimulation element does not have a sharpened end and is positioned relative to the means for securing the surgical apparatus to the tissue structure such that the tissue stimulation element is pressed against the single side of the issue structure and does not pierce the tissue as recited in claim 32 and wherein the stimulation element does not have a sharpened end and is positioned relative to a portion of the anchor that pierces tissue such that the tissue stimulation element is pressed against the tissue and does not pierce the tissue as recited in claim 33. Rather, Hess explains that the electrode 21 (alleged stimulation element) is arranged to pierce tissue. Once again, Hess describes an opposite configuration and teaches away from these claim limitations.

Office Action remarks alleging that the helical electrode 21 is "not responsible" for piercing tissues simply fail to consider the undisputable fact that Hess actually explains that the highly sharpened tip 37, as well as the helical electrode 21, pierce cardiac tissue. Thus, these Office Action remarks are irrelevant and contradict the clear and undisputable teachings of Hess, which specifically describes "a preferred method of permitting the electrode [21] to pierce the cardiac tissue..." Hess (col. 2, lines 56-61) (emphasis added). The Office action has not addressed these determinative facts.

Baker does not cure the multitude of substantial and determinative deficiencies of Hess. Baker also has its own deficiencies.

Claims 32 and 33 recite limitations directed to the stimulation element not having sharpened end. It is alleged that Baker discloses certain dimensions of a needle electrode. As shown in the figure of Baker, this needle electrode, alleged to be a stimulation element, pierces tissue. Thus, the Office Action allegations are irrelevant and moot, and Baker teaches away from claims 32 and 33.

Accordingly, Hess and Baker, even if somehow combined despite teaching away from multiple limitations of claims 32 and 33, fail to disclose each limitation of these claims. Moreover, the Office action remarks in support of the rejection simply ignore undisputable

teachings of the cited references and simply ignore the fact that claims 32 and 33 recite structure that is the opposite of components in the cited references.

Therefore, Applicant respectfully submits that independent claims 32 and 33 are patentable over Hess and Baker. Dependent claims 14, 17, 19, 20 and 42 depend from and incorporate the elements of respective independent claims 32 and 33 and, therefore, are also patentable over the these cited references.

Thus, Applicant respectfully request that the rejection be withdrawn.

V. Claims 14, 32, 34, 36, 37, 40 and 42 Are Patentable Over Rau, Franchi and Daddona

Independent claims 32 and 34 and respective dependent claims 14, 36, 37, 40 and 42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,685,466 to Rau ("Rau") in view of U.S. Patent No. 5,466,255 to Franchi ("Franchi") and U.S. Patent No. 6,091,975 to Daddona ("Daddona").

Rau fails to disclose, and is not related to, "a tissue stimulation element having a diameter of about 0.5mm to 1.0mm and being configured to emit non-ablative stimulation energy that is applied to the tissue structure to determine whether a transmural myocardial lesion has been formed" as recited in claim 32 and "a first tissue stimulation element and a second tissue stimulation element that are configured to emit non-ablative stimulation energy that is applied to the tissue surface to determine whether a transmural myocardial lesion has been formed" as recited in claim 34. Rather, Rau describes a device that is attached to an outer layer of skin. In particular, Rau explains that such devices "are pricked through the skin into the body" to eliminate "the influences of the properties of the skin on the measurement." Rau (col. 1, lines 41-45). Simply because Rau recites a particular dimension does not mean that it applies to claims 32 and 34.

Rau is also understandably silent as to "wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion" as recited in claims 32 and 34. The Office Action refers to certain figures and sections of Rau, but the figures and sections are silent as to these limitations.

Rau also fails to disclose "means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure at a first tissue structure location and pressing the stimulation element against the single side of the tissue structure at a second tissue structure location different than the first tissue

structure location" as recited in claim 32. Instead, Rau describes a needle 1 that penetrates tissue, and this needle 1 is what secures the apparatus to tissue. However, this does not press a stimulation element against a single side of a tissue structure at a different location.

Further, as conceded in page 7 of the Office Action, Rau also fails to disclose 1) an interior portion that is curved, 2) a tissue engagement device carried by a curved interior portion between tissue stimulation elements and configured to secure the carrier to the tissue surface in a deflected and stressed state, and 3) a stimulation element that does not pierce.

Indeed, claim 32 specifically recites, "wherein the stimulation element does not have a sharpened end" and "does not pierce the tissue structure" and claim 34 recites "wherein the first stimulation element and the second stimulation element do not have sharpened ends" and "are pressed against the tissue surface without piercing the tissue surface."

In contrast, the Office action relies on electrode 1 in Rau. As clearly explained by Rau, the electrode is in the form of a "needle point" which is in contrast to the claims that recite a stimulation that does not have a sharpened end. Moreover, Rau clearly explains that such sharpened needle points are used to prick through the skin, *i.e.*, to penetrate tissue. Again, this is in contrast to claims that recite stimulation elements that do not have a sharpened end and that do not pierce tissue.

Franchi and Daddona do not cure these deficiencies such that Rau, Franchi and Daddona, individually and even if somehow combined, fail to disclose each limitation of claim 32. Notably, the remarks on page 7 of the Office action regarding Franchi and Daddona do not even address, or do so in a minimal manner, the conceded deficiencies noted above. Further, these remarks do not disclose how these references disclose each limitation of each claim not disclosed by Rau, noting that Rau has a multitude of substantial and determinative deficiencies.

Franchi is apparently cited for the limited purpose of allegedly disclosing: 1. a flexible carrier having "a curved interior portion" and 2. a tissue engagement device that is carried by the curved interior portion of the carrier between first and second stimulation elements and configured to secure the carrier to the tissue surface in the deflected and stressed state. Office Action (p. 5). The Office Action cites Figs. 6-9 of Franchi, but these figures do not show stimulation electrodes. Further, Applicant notes that claim 34 recites that the flexible carrier is configured such that there is a curved interior portion between first and second end portions (which carry respective first and second stimulation electrodes), and that this curved interior

portion is in spaced relation to the tissue surface when the end portions (which carry respective first and second stimulation electrodes) are in contact with the tissue surface and the carrier is in an unstressed state and, in addition, that a tissue engagement device is carried by the curved interior portion, between the first and second stimulation elements. Figs. 6-9, however, do not show this structure since claws 9 at the ends of the sheet 4 (which is apparently alleged to be a stimulation element). Franchi explains that claws are distributed "around the periphery of the sheet 4" or, in other words, on an outer edge of the sheet 4. Franchi (col. 4, lines 17-18) (emphasis added). Thus, Franchi describes a configuration that is the opposite of the configuration recited in claim 34 since the cited claws 9 are positioned around a periphery, or outside of, alleged stimulation elements. Thus, in addition to these deficiencies, Franchi also teaches away from claim 34. Moreover, Franchi explains that the claws 9 are for "easy penetration of the myocardium" and thus do not disclose, and teaches away from, stimulation elements that do not have sharpened ends and that do not penetrate tissue. Franchi (col. 4, lines 21-27 (emphasis added).

Daddona is cited for the very limited purpose of allegedly disclosing a structure for securing a device to cardiac tissue. Office Action (p. 6). Daddona, however, does not cure the substantial deficiencies discussed above. Moreover, Daddona is specifically directed to devices "for piercing the skin of a patient." Daddona (Abstract) (emphasis added). For example, Daddona explains that microprtotusions 4 are sized and shaped "for piercing" the outermost layer of skin. Daddona (col. 3, lines 12-14) (emphasis added). Thus, Dadonna describes a configuration that is the opposite of the configuration recited in claims 32 and 34. Further, given the structure described, Daddona teaches away from claims 32 and 34.

Applicant, therefore, respectfully submits that the multitude of deficiencies of the cited references, individually and collectively, clearly demonstrate that claims 32 and 34 are patentable over Rau, Franchi and Daddona, even if somehow combined as alleged despite multiple references teaching away from Applicant's claims. Dependent claims 14, 36, 37, 40 and 42 depend from and incorporate the elements of respective independent claims 32 and 34 and, therefore, are also believed patentable over the cited references.

Accordingly, Applicant respectfully request that the rejection be withdrawn.

VI. Claim 41 Is Patentable Over Rau, Franchi, Daddona and Baker

Dependent claim 41 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over four references: Rau, Franchi, Daddona and Baker, all of which have been discussed above. Dependent claim 41 incorporates the limitations of independent claim 34 and, therefore is also believed patentable over the cited references in view of the deficiencies discussed above.

Accordingly, Applicant respectfully request that the rejection be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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